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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,569	02/21/2002	Gholam-Reza Zadno-Azizi	38349-0102D	4156

7590

04/18/2003

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EXAMINER

CHATTOPADHYAY, URMI

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 04/18/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/081,569

Applicant(s)

ZADNO-AZIZI ET AL.

Examiner

Urmi Chattopadhyay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 29 January 2003 is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>8</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The Request for Reconsideration filed 1/29/03 has been entered as Paper No. 7. The change made to Figure 5 has been approved by the examiner. Because the preliminary amendment filed 11/7/02 was filed prior to the mailing date of the non-final office action (11/14/02), this office action is of non-final status. Claims 20-25 have been added, so claims 16-25 are being considered for further examination on the merits.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 16-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no support in the specification for a bronchial sub-branch obstruction device for reducing the size of a lung with all the required structural elements or a conduit configured to be passed down a trachea. The current invention is a body *fluid* control device for urinary, venous or pulmonic placement (see page 2, lines 13-14 and page 3, lines 5-6).

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4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 23 is indefinite because it is claiming two distinct species. The elongate passage and outer sheath are not equivalents in the art, and are in fact two distinct species shown in Figures 11 and 12, respectively. Therefore, use of the word "or", which indicates equivalence, between "elongate passage" and "outer sheath" renders the claim indefinite.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 20-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knapp et al. (USPN 5,984,965 as cited in applicant's IDS) in view of Andersen et al. (USPN 5,411,552 as cited in applicant's IDS).

Knapp et al. discloses a stent for placement in a body passage, including a vascular passage (column 1, lines 10-16), with all the elements of claims 20 and 23, but is silent to the valve being dimensioned for pulmonary placement. A fluid-flow control device comprises a one-way valve (column 2, lines 41-48) configured to restrict fluid flow to one direction (column

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5, lines 27-47). The fluid-flow control system of claim 23 further includes an elongate passage (guide wire mentioned in column 6, lines 12-24) for positioning the valve, which valve is dimensioned to be guidable on the elongate passage. Andersen et al. teaches replacing insufficient valves within the pulmonary artery with replacement valves. See column 3, lines 43-46. This replacement restores proper functioning of the pulmonary artery by reestablishing one-directional flow therein. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Andersen et al. to dimension the valve of Knapp et al. for pulmonary placement in order to, upon implantation in a pulmonary artery suffering from valvular insufficiency, restore uni-directional flow within the pulmonary artery. Placement in the pulmonary artery would also treat this vascular passage if afflicted with hard, irregular masses that develop therein (see Knapp et al. column 1, lines 10-16).

Knapp et al., as modified by Andersen et al., does not disclose expressly that the valve has an outer diameter of 0.349 inches, as required by claims 21 and 24. However, it appears in column 1, lines 10-16 and column 6, lines 12-23 that the stent of Knapp et al. will be dimensioned to specifically fit the body passage it is being implanted into to treat, including vascular passages. Because the diameter of the pulmonary artery varies from person to person, the correct size valve will also vary from person to person. Therefore, it would be obvious to one of ordinary skill in the art to make the valve of Knapp et al. and Andersen et al. have an outer diameter of 0.349 inches if that is the correct dimension for the patient.

Claims 22 and 25, see Figure 3B for a valve body having a slit (26) through which fluid can flow.

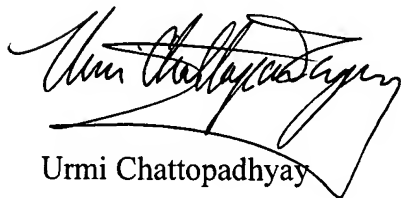
Response to Arguments

8. Applicant's arguments filed 1/29/03 have been fully considered but they are not persuasive. Applicant argues that the written description provides more than adequate support for all the elements of claims 16-19. Examiner disagrees. As can be seen from the charts provided by applicant in Appendix A, the limitations of the claimed invention are much more specific than the recited sections of the specification. The broad disclosure of a flow control device for pulmonic placement does not sufficiently support the claiming of a bronchial sub-branch obstruction device with further structural limitations. With respect to the functional language in the claims, whether or not the fluid-flow control device disclosed in the specification would inherently possess the claimed functionality, the ability of the fluid-flow control device to perform those functions must still be disclosed in the specification in "full, clear, concise, and exact terms" (quotation of first paragraph of 35 U.S.C. 112). Therefore, the rejection of claims 16-19 is maintained.

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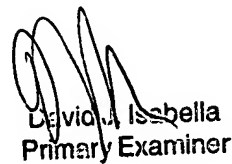
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 305-3590. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.



Urmi Chattopadhyay

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David J. Isabella
Primary Examiner

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April 14, 2003